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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/215,095 12/18/98 BECKER

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EXAMINER
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HM12/0612

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BORIN, M	
ART UNIT	PAPER NUMBER

1631

DATE MAILED:

06/12/01

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Advisory Action

Application No.  
09/215,095

Applicant(s)  
Becker et al

Examiner  
Michael Borin

Art Unit  
1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED May 10, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on May 10, 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE:

4. ☐ Applicant's reply has overcome the following rejection(s):
5. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
SEE ATTACHED
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):  
Claim(s) allowed: \_\_\_\_\_  
Claim(s) objected to: \_\_\_\_\_  
Claim(s) rejected: 66-69, 72-76, and 78-88
9. ☐ The proposed drawing correction filed on \_\_\_\_\_ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
11. ☐ Other:

MICHAEL BORIN  
PRIMARY EXAMINER  
ART UNIT 1631

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### **DETAILED ACTION**

1. Response to final rejection 05/10/01 is acknowledged. No substantial changes to claims has been proposed; a minor grammatical correction of claim 85 is made. Claims 66-69, 72-76, 78-88 are under examination. Claims 70, 71, 77 remain withdrawn from consideration as drawn to non-elected species.

#### ***Information Disclosure Statement***

2. The supplemental Information Disclosure Statements have been submitted on 4/27/01 after final Office action had been mailed out. Because no petition has been concurrently submitted, and no fee has been paid, the supplemental IDS will be placed in the file but will not be considered. See 37 CFR §1.17(I)(1) requirements.

#### ***Claim Rejections - 35 USC § 102 and 103.***

3. Claims 66-69, 72,74,78,79,82-86 remain rejected under 35 U.S.C. 102(b) as anticipated by Kiesser et al. (US Patent 5,739,091)

Applicant argues that the granule of invention is a "multi-layered granule including a protein matrix surrounding a seed". However, the invention as claimed does not recite multiple layers. As for the protein matrix surrounding a seed, the granules are prepared by layering the enzyme around dry pre-mix. In regard to the latter, applicant cites description of preparation of the referenced granules (col. 4, lines 21-27) which demonstrates that the mix of granule material during preparation

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is mixed with water to a homogenous composition. This description, however, does not exclude that the pre-mix serves as a seed and, further, remains in the homogenated composition as a solid (note, that the reference teaches that some of the granule's constituents are insoluble - see col. 1, line 34, line 2, line 66).

Further, applicant argues that the reference does not teach protein matrix of granules as claimed. However, the claimed limitations of the content of the granule's protein matrix are limited to protein, sugar and polysaccharide. The reference, on the other hand, teaches enzyme granules comprising enzymes, sugars, such as mono- or di- saccharides, and a filler, such as cellulose. Thus the referenced and claimed granules are not distinct. As for other components of the referenced granule, the "comprising" claim language of the instant claims is open to any other excipients and components.

Applicant argues that there is no disclosure of sugar as a water-soluble filler or binder. However, sugars are not claimed as such, and even if they had been, it would be considered as an intended use limitation.

Further, applicant argues that there is no clear teaching in the reference that a protein matrix is comprised of a protein mixed with a combination of a sugar and a polysaccharide. See column 1, lines 31-39, 60-67, column 2, line 66 to col. 3, line 4, teaching that the granules comprise enzyme or enzyme mixture, sugars, such as mono- or di- saccharides, and a filler, such as cellulose.

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4. Claims 75,76,80,81,87,88 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kiesser et al. (US Patent 5,739,091).

Applicant questions expectation of success in picking certain enzymes (such as those broadly claimed in claim 75). Applicant does not provide any factual evidence that selecting any particular enzyme, from "enzymes" broadly taught by the reference, may result in unsuccessful granule preparation. Further, all enzymes recited in claim 75 are disclosed in the reference (col. 2, lines 10-12). As for selection of filler, as cellulose derivatives are well known to be used for this purpose, selection of a particular cellulose derivative would be obvious for an artisan to be achieved in a way of ordinary optimization.

5. Claims 66-69,72-74,76, 78-86 remain rejected under 35 U.S.C. 103(a) as obvious over Scott (EP 272923).

Applicant's arguments are considered but are not deemed to be persuasive. The arguments are limited to the description of the reference and are concluded with the statement that the reference does not suggest claimed granules wherein an enzyme is admixed with a combination of a sugar and polysaccharide. The reference, however, teaches granules which include enzyme, sugar (glucose), low molecular weight polysaccharide (e.g., cellulose), and optionally synthetic polymer. Although the reference does not teach protein core layered over a seed particle and coating the particle, it would be conventional and within the skill of the art to prepare such granule because the techniques of using a seed particle for the intended purpose of forming a granule and coating the granule to

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protect its content are well known in the pharmaceutical art, and are within the skill in the art to which this invention pertains. The latter argument presented in the rejection is not addressed in the applicant's traverse.

6. Claims 66-69, 72-76, 78-88 remain rejected under 35 U.S.C.103(a) as obvious over Martussen (EP 304332).

As in the case of the previous rejection over Scott, applicant declined to comment on examiner's argument that it would be conventional and within the skill of the art to prepare such granule because the techniques of using a seed particle for the intended purpose of forming a granule is well known in the pharmaceutical art, and are within the skill in the art to which this invention pertains and that addition of such ingredients as sugars and polysaccharides would be *prima facie* obvious when the enzyme granulates are to be used as nutrient additives, because the reference teaches that in such cases the core could contain sugar, or starch, or protein.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

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Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 5, 2001    **MICHAEL BORIN, PH.D**  
                    **PRIMARY EXAMINER**

mlb

A handwritten signature in cursive script, appearing to read "Michael Borin", written in dark ink.